

PATENT APPLICATION

Cross Reference to Related Applications

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3 This application claims the benefit of U.S. Provisional Application No. 60/189,838, filed
4 March 16, 2000 by Merril et al., entitled "System and Method for Controlling Force Applied
5 to and Manipulation of Medical Instruments," which is incorporated herein by reference in its
6 entirety.

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Background of the Invention

10 Minimally invasive techniques for providing medical examinations and therapies frequently
11 employ endoscopes, such as a bronchoscope, ureteroscope, or flexible sigmoidoscope.

12 Endoscopes such as these typically employ fiber optic or CCD imaging devices to enable the

13 practitioner to visually inspect otherwise inaccessible areas of the anatomy such as the lungs,

the ureter and kidneys, the colon, etc. These endoscopes also typically contain a tube, called

17 administering and removing liquids or other material, the working channel of an endoscope is

1 variety of other tools.
2
3 Manipulation of these tools requires simultaneous manipulation or stabilization of the
4 endoscope, along with manipulation of the working channel tool itself. The endoscope can
5 typically be maneuvered along three, four or more degrees of freedom, including insertion
6 and withdrawal, rotation, and tip flexion in one or two dimensions (up/down and/or
7 left/right). The working channel tool is maneuvered along an additional two or more degrees
8 of freedom, including insertion/withdrawal, rotation, and tool actuation, etc. Tool actuation
9 can include, for example, opening and closing the jaws of a biopsy forceps, controlling the
10 plunge of a biopsy needle, actuating a cauterization or ablation tool, pulsing a laser, or
11 opening and closing a snare or basket. The tasks of manipulating and stabilizing the three or
12 more degrees of freedom of the endoscope, while simultaneously manipulating the multiple
13 degrees of freedom of the working channel tool are difficult to perform, and frequently the
14 practitioner uses an assistant to manipulate one or more of the degrees of freedom, such as
15 working channel tool actuation.

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Summary of the Invention

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19 The present invention relates to a device or system that extends the functionality of the
20 working channel of an endoscope by adding devices for sensing motion of the working
21 channel tool and for application of motive force to assist the practitioner in manipulation of
22 the instrument in the working channel.

23

24 In one mode of use, the system uses drive wheels driven by a motor or other device to permit

1 the practitioner to quickly exchange working channel tools, by smoothly moving the current
2 tool out of the working channel, and then quickly moving in the new tool to a point just short
3 of exiting the working channel. At this point the practitioner takes over and performs the fine
4 motor skills necessary to move the tool out of the endoscope and into a position to interact
5 with the anatomy. In another mode of operation the physician manipulates tools manually
6 and is provided with tactile guidance via a set of driven or braked drive wheels. One form of
7 guidance is the provision of notification that the tool is approaching the end of the endoscope
8 and is about to emerge from the endoscope. A braking or other tactile force would signal
9 nearing the end of the working channel, enabling the user to move the tool quickly within the
10 working channel without danger of moving the tool too rapidly out of the working channel,
11 thereby reducing the risk of damage or injury to tissue adjacent the distal end of the
12 endoscope.

13

14 In another embodiment, the sensor and drive assembly is coupled to a catheter through which
15 instruments and tools are passed into the vascular system. For instance, in the process of
16 implantation of a heart pacing lead, the cardiologist must make a number of fine adjustments
17 in the position of a guide catheter, then attempt to stabilize it while inserting an additional
18 element through the lumen of the stabilized catheter. In one mode, the sensor/drive assembly
19 is commanded to maintain a position using passive or active braking force. In another mode,
20 the tip of the catheter is instrumented and an active mechanism commands insertion/retraction
21 and roll increments to stabilize the actual position of the distal end.

22

23 In yet another embodiment, the sensor and drive assembly is instrumented with strain gauges
24 or other devices to detect forces encountered at the distal end of the catheter or working

1 channel tool. These forces are then amplified and displayed to the user via a motor or other
2 motive mechanism.

3

4 In another embodiment, the sensor and drive assembly detect and modify motions, for
5 example detecting and filtering out high frequency jitter caused by the user. This
6 superstabilization mode is useful in situations where fine motor control is required.

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8 In another embodiment, signals from a device inserted in the working channel are used to
9 command the motive device to maintain a particular quality of electrical contact with the
10 anatomy. In this situation, electrical impedance is changed by the force of contact. A desired
11 quality of contact is initially attained by the physician, then the device is commanded to
12 control contact force automatically to maintain the particular quality of contact.

13

14 The above and still further features and advantages of the present invention will become
15 apparent upon consideration of the following detailed description of specific embodiments
16 thereof, particularly when taken in conjunction with the accompanying drawings wherein like
17 reference numerals in the various figures are utilized to designate like components.

18

19 **Brief Description of the Drawings**

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21 FIG. 1a illustrates an unmodified endoscope with working channel and working channel tool.

22

23 FIG. 1b illustrates an endoscope modified to provide a sensor and control element in
24 accordance with the present invention.

1
2 FIG. 2 illustrates an endovascular tool inserted into the vascular anatomy, combined with a
3 sensor and control element in accordance with the present invention.

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5 FIG. 3 illustrates an axial motion sensor control element in accordance with the present
6 invention.

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8 FIG. 4 illustrates addition of a rotational motion sensor and control element to the device in
9 FIG. 3.

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DETAILED DESCRIPTION

FIGURE 1a illustrates an unmodified endoscope of the prior art, showing the endoscope body 2 attached to the endoscope tube assembly 3. Working channel tool 4 is inserted into working channel orifice 6 in endoscope body 2. Working channel tool 4 slides through working channel tube 1 and exits the distal end of endoscope tube assembly 3 through working channel orifice 5.

FIGURE 1b illustrates one embodiment of a motion sensor and control element 10 of the present invention, which is affixed to the working channel orifice 6 of an endoscope. Working channel tool 4 passes through motion sensor and control element 10 and through working channel orifice 6. Normal manipulation and operation of the working channel is possible through the body of motion sensor and control element 10. Motion sensor and control element 10 can assist in the control of the working channel tool 4, as exemplified.

1 the embodiments presented below.

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3 The working tool 4 may be any of a variety of medical instruments used in endovascular
4 procedures, endoscopy or other medical procedures. For example, the working tool can be a
5 guidewire, a catheter, a heart pacing lead, or a stylet. The tool end that enters and operates on
6 or interacts with the body can include one or more of any of a variety of tools, such as a blade,
7 a serrated edge, a biopsy tool, a trocar tip, an ultrasonic tool, a needle, a vibrating tip, a
8 suturing tool, a retractor, an electrosurgical cutter, an electrosurgical coagulator, a forceps, a
9 needle holder, scissors, an irrigator, an aspirator, a medicator, a laser tool, a cryogenic tool, a
10 flexible steering or guiding tip, and/or a camera. For simplicity, the term "working channel"
11 as used herein is intended to refer to any tube that can guide a medical tool, including
12 catheters, tubes, endoscopic working channels, or other channels.

13

14 FIGURE 2 illustrates an endovascular application of the motion sensor and control element
15 10 of the present invention. Motion sensor and control element 10 is coupled to introducer
16 sheath 7 (which can be considered a "working channel" herein), which pierces skin 8 and the
17 wall of blood vessel 9. Elongated endovascular tool 4 passes through motion sensor and
18 control unit 10, through introducer sheath 7, and into the lumen of blood vessel 9.

19

20 FIGURE 3 illustrates one embodiment of sensor and control element 10 which measures the
21 motion of and applies force to the body of the working channel tool 4 in its translational
22 degree of freedom. Motion sensor and control element 10 contains a sensor device for
23 measuring translational motion of the body of working channel tool 4. As the elongate
24 portion of working channel tool 4 passes between motion sensing and control whee'

1 idler wheel 13, it causes rotation of each wheel. Wheel 18 is affixed to shaft 15 of an actuator
2 12 that is supported by bracket 20. In turn, transparent optical encoder disk 14 is affixed to
3 the opposite end of motor shaft 15. Encoder reader 16 passes light through transparent
4 encoder disk 14. As transparent encoder disk 14 rotates, marks imprinted on the surface pass
5 in front of the light source, occluding alternately light passing through the disk. A plurality of
6 light sensors in encoder reader 16 measure the varying light and dark patterns and determine
7 the amount and direction of rotational motion of encoder disk 14. Control unit 24 receives
8 motion signals from encoder reader 16 corresponding to translational motion of working
9 channel tool 4.

10

11 Actuator 12 is operative to provide forces on the working channel tool 4 in its translational
12 degree of freedom, as transmitted by control wheel 18 to the tool 4. The actuator 12 is
13 controlled by control signals from the control unit 24. In some embodiments, the control unit
14 24 can determine the amount of force to be output from actuator 12 by examining the current
15 signals from the encoder reader 16 indicating the current position or motion of the tool 4, and
16 then control the actuator 12 to output that force. For example, the current position of the tool
17 4 may indicate when force is to be output and/or the amount of force to be output, as
18 described below.

19

20 Control unit 24 can include a microprocessor, ASIC, or other type of processor or controller,
21 for example. Other types of sensors, besides the optical type of sensor described above, can
22 also be used to sense the position and/or amount of motion of working channel tool 4 to
23 determine insertion distance; for example, analog potentiometers, other types of optical
24 sensors, magnetic sensors, etc., can be used. Some embodiments may use absolute sensors

1 instead of the relative sensor described above; for example, successive markings can be
2 placed on the tool 4 and detected by an optical or other type of detector when the markings
3 are moved past the sensor to determine the position of the tool. Actuator 12 is an
4 electronically-controlled device that modifies the force on the tool 4. For example, actuator
5 12 can be a DC motor, stepper motor, moving magnet actuator, voice coil, hydraulic or
6 pneumatic actuator, or a variety of other types of actuators able to output a force on the
7 working tool 4. Actuator 12 can also be a passive actuator, such as a magnetic particle brake,
8 fluid brake, or other form of brake, which causes a controllable resistance to motion of the
9 tool 4 based on control signals from control unit 24. Multiple actuators 12 may also be used,
10 of same or differing types.

11

12 In one mode of the present invention, the total distance of insertion of the working channel
13 tool is measured and controlled by the motion sensor and control element. For example,
14 control unit 24 can be provided with, or can measure (using the sensor) the total insertion
15 distance of working channel tool 4. This distance can be used in assisting control of the tool
16 4. For example, the user or practitioner can manually move the tool 4 within the working
17 channel. However, when a preset limit, point, or distance is approached by the front (distal)
18 end of the tool, such as the exit point of the channel, control signals can be transmitted to
19 actuator 12 to produce torque necessary to slow and then halt further motion of motion
20 sensing and control wheel 18, thereby slowing and then halting further insertion of working
21 channel tool 4.

22

23 In other modes of operation, if the practitioner inserts a tool into the working channel, the
24 actuator 12 can be used to move the tool 4 into and through the working channel, to a point

1 just short of exiting the channel, so that the tool is then ready for manual use by the
2 practitioner, i.e. the practitioner then moves the tool out of the endoscope and into a position
3 to interact with the anatomy. The control unit 24 can use the signals from sensor of the
4 element 10 to determine the position of the tool. In some embodiments, the drive wheel
5 driven by actuator 12 can permit the practitioner to quickly exchange working channel tools,
6 by smoothly moving a current tool out of the working channel, and then quickly moving in
7 the newly-inserted tool to a point just short of exiting the working channel at its other end.

8

9 In yet another mode of operation, the physician can manipulate the tools manually and is
10 provided with tactile guidance via the actuator 12. One form of guidance is the provision of a
11 haptic notification that the tool is approaching or has approached a desired location or has
12 traveled a predetermined distance. For example, the haptic notification can indicate that the
13 tool has reached the end of the working channel or catheter and is about to emerge from the
14 channel. A braking or resistive force, or other tactile force, can signal that the tool is nearing
15 the end of the working channel, enabling the user to move the tool quickly within the working
16 channel without danger of moving the tool too rapidly out of the working channel, thereby
17 reducing the risk of damage or injury to tissue adjacent the distal end of the endoscope. The
18 notification can take a variety of forms, from a single pulse of resistance, a barrier force
19 (continuing resistive force), a vibration, damping force (having a magnitude based on velocity
20 of the tool in one or more directions), spring force, a series of particular jolts or actuated
21 detents, etc. In another embodiment, the notification can indicate each increment or
22 predetermined distance that the tool has been moved by the user. For example, a detent,
23 vibration, or jolt can be output by actuator 12 for each 10 centimeters that the tool is moved
24 into the working channel, or the notification can occur at half or quarter points along the

1 channel.

2

3 In another embodiment, the sensor and control element 10 can provide forces on a catheter

4 through which instruments and tools are passed into the vascular system. For instance, in the

5 process of implantation of a heart pacing lead, the cardiologist must make a number of fine

6 adjustments in the position of a guide catheter, then attempt to stabilize it while inserting an

7 additional element (such as a lead tool) through the lumen of the stabilized catheter. In one

8 mode, the sensor and control element 10 can be commanded to output forces on the catheter

9 to maintain it at a desired position using passive or active force from actuator 12. In another

10 embodiment, the tip of the catheter can be instrumented and an active mechanism may

11 command insertion/retraction and roll increments of the catheter to stabilize the actual

12 position of the distal end.

13

14 In another embodiment, the sensor and control element 10 can detect and modify motions of

15 the working tool 4. For example, the sensor of element 10 can detect high frequency jitter

16 caused by the user, based on short, undesired motions or oscillations the user may be

17 conveying to the tool. These motions can then be filtered out after being detected by

18 providing a force in the opposite direction by actuator 12 to cancel or reduce the magnitude of

19 the jitter. This superstabilization mode can be useful in situations where fine motor control is

20 required.

21

22 In another embodiment, signals from a device or tool inserted in the working channel are used

23 to command the motive device/tool to maintain a particular quality of electrical contact with

24 the anatomy, e.g. in a heart pacing lead application. For this type of situation, electrical

1 impedance is typically changed if the magnitude of the force of contact of the tool with the
2 anatomical part is changed. The present invention can be used to maintain or achieve a
3 desired quality of contact (or contact force). For example, a desired quality of contact can be
4 initially attained by the physician using the tool manually. Then, the sensor and control
5 element 10 can be commanded to control the contact force automatically to maintain that
6 particular quality of contact by detecting the electrical impedance resulting from the desired
7 contact; if the electrical impedance goes above or below a desired threshold, the force on the
8 tool from actuator 12 is adjusted to provide the desired electrical contact. Other embodiments
9 may use a force sensor on the distal end of the tool to detect the current contact force and
10 maintain a desired contact force.

11

12 In another embodiment of the invention, the forces on the working channel tool 4 applied by
13 the user are measured and used in force determination, where motion sensing and control unit
14 10 can effectively amplify or reduce forces applied by the user to tool 4. In this embodiment,
15 handle 17 can be disposed adjacent force-torque sensor 19 which in turn is disposed adjacent
16 working channel tool 4 such that translational force applied by the user to working channel
17 tool 4 via handle 17 is sensed by force-torque sensor 19. A control algorithm described
18 below and residing in control unit 24 receives signals resulting from applied force measured
19 by force-torque sensor 19 and in response produces control signals which are transmitted to
20 actuator 12 to control the motion of wheel 18. Wheel 18 can be moved either by force
21 applied by actuator 12 or by frictional forces applied via working channel tool 4. When
22 working channel tool 4 is held motionless by the user, force applied to wheel 18 via shaft 15
23 of actuator 12 is opposed by, and therefore sensed by, torque sensor 22 which is attached to
24 bracket 20 which is in turn fastened to base 11 of sensing and control element 10. Force

1 applied to working channel tool 4 by control wheel 18 is sensed by torque sensor 22 and
2 denoted F_W . This force is added to force applied by the user (F_U) to produce the effective
3 force at the distal end of the working channel tool F_{WC} , as expressed in the following equation
4 of equilibrium:

5

6 Equation 1 $F_{WC} = F_U + F_W$

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8 The control algorithm described below and contained in controller 24 dynamically modifies
9 the force applied by the wheel 18, F_W , to control working channel tool force, F_{WC} , in response
10 to force applied by the user F_U . In particular, if the desired relationship between user applied
11 forces and working tool forces is expressed by function $f()$ as:

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13 Equation 2 $F_{WC} = f(F_U)$

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15 Combining these equations and solving for F_W provides the following control algorithm:

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17 Equation 3 $F_W = f(F_U) - F_U$

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19 Control unit 24 receives signals corresponding to user applied force F_U and control wheel
20 force F_W and adjusts control signals transmitted to actuator 12 to implement the control
21 algorithm of equation 3.

22

23 In a different embodiment, the sensor and control element 10 can be instrumented with strain
24 gauges or other devices to detect or measure forces encountered at the distal end of the

1 catheter or working channel tool. These forces can then be amplified and displayed to the
2 user via actuator 12 or other motive mechanism to allow the practitioner to more easily
3 control or determine the behavior of the distal end of the moved catheter or tool.
4

5 FIGURE 4 illustrates another embodiment of the sensing and control element 10 of the
6 present invention, in which rotation and torque of the tool 4 is sensed and controlled in
7 addition to sensing translation and controlling axial force as described in Figure 3. In Figure
8 4, as the elongated portion of working channel tool 4 rotates between motion sensing and
9 control wheel 28 and idler wheel 26, it causes rotation of each wheel. Wheel 28 is affixed to
10 shaft 29 of actuator 30. In turn, transparent optical encoder disk 34 is affixed to the opposite
11 end of motor shaft 29. Encoder reader 38 passes light through transparent encoder disk 34.
12 As transparent encoder disk 34 rotates, marks imprinted on the surface pass in front of the
13 light source, occluding alternately light passing through the disk. A plurality of light sensors
14 in encoder reader 38 measure the varying light and dark patterns and determine the amount
15 and direction of rotational motion of encoder disk 34. Control unit 24 receives motion
16 signals from encoder reader 38 corresponding to rotational motion of working channel tool 4.
17 Control unit 24 measures the rotation of working channel tool 4 using these signals.
18

19 Actuator 30 can be similar to actuator 12, where control unit 24 provides control signals to
20 actuator 30 to output a force in the rotational degree of freedom of the tool 4. As described
21 above, both the sensor 34/38 and actuator 30 can take a variety of different forms.
22

23 In one embodiment, when a preset limit to rotation is approached by the tool 4, a control
24 signal is produced by control unit 24 and transmitted to actuator 30 to produce torque

1 necessary to slow and then halt further motion of motion sensing and control wheel 28,
2 thereby slowing and then halting further rotation of working channel tool 4. Other
3 embodiments can be similar to those described above for the translational sensing and
4 actuation of the tool 4; for example, a haptic indication can be output to the user when the
5 tool 4 is rotated a predetermined rotational distance (e.g., number of degrees).

6

7 In some embodiments of element 10 of Fig. 4, the torque applied by the user to working
8 channel tool 4 can be measured, and motion sensing and control unit 10 can be used to
9 amplify or reduce the torques applied by the user to tool 4. In Figure 4, the handle 17 is
10 disposed adjacent a force-torque sensor 19 which in turn is disposed adjacent working
11 channel tool 4 such that rotational force applied by the user to working channel tool 4 via
12 handle 17 is sensed by force-torque sensor 19. A control algorithm described below and
13 residing in control unit 24 receives signals resulting from applied force measured by force-
14 torque sensor 19 and in response produces control signals which are transmitted to actuator
15 30 to control the motion of wheel 28. Wheel 28 can be moved either by force applied by
16 motor 12 or by frictional forces applied via working channel tool 4. When working channel
17 tool 4 is held motionless by the user, force applied to wheel 28 via shaft 29 of actuator 30 is
18 opposed by, and therefore sensed by torque sensor 32 which is attached to bracket 36 which is
19 in turn fastened to base 11 of sensing and control element 10. Torque applied to working
20 channel tool 4 by control wheel 28 is sensed by torque sensor 32 and denoted T_w . This
21 torque is added to torque applied by the user (T_u) to produce the effective torque at the distal
22 end of the working channel tool T_{wc} , as expressed in the following equation of equilibrium:
23 Equation 4 $T_{wc} = T_u + T_w$

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1 The control algorithm described below and contained in controller 24 dynamically modifies
2 the torque applied by the wheel 28, T_w , to control working channel tool torque, T_{WC} , in
3 response to force applied by the user T_U . In particular, if the desired relationship between
4 user applied torque and working tool torque is expressed by function $q()$ as:

5 Equation 5 $T_{WC} = q(T_U)$

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7 Combining these equations and solving for T_w provides the following control algorithm:

8 Equation 6 $T_w = q(T_U) - T_U$

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10 Control unit 24 receives signals corresponding to user applied torque T_U and control wheel
11 torque T_w and adjusts control signals transmitted to motor 30 to implement the control
12 algorithm of equation 6.

13

14 The sensor 19 can include two sensors in appropriate embodiments: one sensor to measure
15 the axial force applied by the user to the tool 4, and another sensor to measure the torque
16 applied to the user to the tool 4.

17

18 Thus, sensing and control unit 10 as shown in figure 4 can provide rotational or translational
19 position control, as well as translational force and rotational torque control to working
20 channel tools. As shown in figure 2, sensing and control unit 10 can be used to control any
21 elongated medical instrument, such as a catheter used in interventional radiology.

22

23 While this invention has been described in terms of several preferred embodiments, it is
24 contemplated that alterations, permutations, and equivalents thereof will become apparent to

1 those skilled in the art upon a reading of the specification and study of the drawings. For
2 example, many different types of sensors and actuators can be used to sense tool position or
3 motion and to output tactile sensations to the user. Furthermore, many of the features
4 described in one embodiment can be used interchangeably with other embodiments.
5 Furthermore, certain terminology has been used for the purposes of descriptive clarity, and
6 not to limit the present invention.

What is claimed is: